

**NxStage Medical, Inc.  
NxStage Dosing Calculator  
510(k) Premarket Notification****JUL 11 2013**

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content contained in this 510(k) summary has been provided in conformance with 21 CFR §807.92

**A. Date:** June 5, 2013

**B. Submitter's Information:**

**Name:** NxStage Medical, Inc.

**Address:** 350 Merrimack Street  
Lawrence, MA 01843  
United States

**FDA Establishment  
Owner/Operator  
Number:** 9045797

**Contact Person:** Gregor Dzialas  
Regulatory Affairs Manager

**Phone:** (978) 332-5985  
**Fax:** (978) 687-4750

**Manufacturer:** NxStage Medical, Inc.  
350 Merrimack Street  
Lawrence, MA 01843  
United States

**FDA Establishment  
Registration Number:** 3003464075

**Sterilization Site:** Not Applicable

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**C. Device Name:**

<b>Trade/Proprietary Name:</b>	NxStage Dosing Calculator
<b>Common/Usual Name:</b>	Dosing Calculator
<b>Classification Name:</b>	Hemodialysis System and Accessories
<b>Regulation Number:</b>	21 CFR 876.5820
<b>Product Code:</b>	FKP –Hemodialysis System and Accessories
<b>Device Classification:</b>	Class II
<b>Device Panel:</b>	Gastroenterology-Urology (GU)/Gastro-Renal (GRDB)

**D. Substantial Equivalence:**

The NxStage System Dosing Calculator is substantially equivalent to the Fresenius Pack H Hemodialysis Urea Kinetic Modeling Software Program, K955423.

**E. Device Description/Indications for Use:**

**Device Description:**

The NxStage Dosing Calculator is a software modeling program designed to assist physicians and licensed healthcare practitioners in prescribing chronic hemodialysis therapy with the NxStage System One and NxStage Cartridge with pre-attached dialyzer. It allows physicians and licensed healthcare practitioners to determine a range of appropriate treatment frequencies, treatment durations, and therapy fluid volumes. The program incorporates formulas that have been published in peer reviewed journals of medicine and models treatment parameters for a range of possible treatment frequencies, volumes, and durations. This is a tool only and does not replace the need for the physician or licensed healthcare practitioner to make an independent determination of the therapy best suited for the patient.

**Indications for Use:**

The NxStage Dosing Calculator is intended to provide chronic hemodialysis prescription options with the NxStage System One and Cartridge with pre-attached dialyzer based on patient and treatment parameters. With a specified set of algorithms, it automatically performs calculations that are typically done by a physician or licensed healthcare practitioner. The algorithms used have been established and documented in scientific literature.

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**F. Technological Characteristics:**

The proposed device has the same technological characteristics and is similar in design and configuration as the predicate device.

**G. Summary of Non-Clinical Test/Performance Testing - Bench**

The information and data provided in this submission clearly describe the proposed device and demonstrate that the device is adequately designed for the labeled indications for use and substantially equivalent to predicate device. Performance, verification and validation testing was conducted to characterize performance of the proposed device. Verification and validation testing was conducted to characterize performance of the proposed device. This included testing for software readiness, software design review, and usability.

All predetermined acceptance criteria were met. Results of this testing also document that the proposed NxStage Dosing Calculator is substantially equivalent to the predicate device and is suitable for the labeled indications for use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

July 11, 2013

NxStage Medical, Inc.  
% Gregor Dzialis  
Regulatory Affairs Manager  
350 Merrimack Street  
Lawrence, MA 01843

Re: K130460  
Trade/Device Name: NxStage Dosing Calculator  
Regulation Number: 21 CFR§ 876.5820  
Regulation Name: Hemodialysis system and accessories  
Regulatory Class: II  
Product Code: FKP  
Dated: June 5, 2013  
Received: June 7, 2013

Dear Gregor Dzialis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.  
Director  
Division of Reproductive, Gastro-Renal,  
and Urological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

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**Indications for Use**

**510(k) Number (if known):** K130460

**Device Name:** NxStage Dosing Calculator

**Indications for Use:** The NxStage Dosing Calculator is intended to provide chronic hemodialysis prescription options with the NxStage System One and Cartridge with pre-attached dialyzer based on patient and treatment parameters. With a specified set of algorithms, it automatically performs calculations that are typically done by a physician or licensed healthcare practitioner. The algorithms used have been established and documented in scientific literature.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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**(Division Sign-Off)**

**Division of Reproductive, Gastro-Renal, and  
Urological Devices**

**510(k) Number**           K130460